REMARKS

I. Introduction – Claim Status

This Amendment Pursuant to 37 C.F.R. §§1.114 is submitted in response to the outstanding Office Action of December 5, 2001, and subsequent to a Notice of Appeal filed May 21, 2001. A Request for Continued Examination (RCE) Under 37 CFR § 1.114 and a Petition for Extension of Time with fee are filed concurrently herewith. The Office Action indicates that claims 1-21 are pending, and claims 13-21 are withdrawn from further consideration. In the present amendment, claims 1, 9, and 10 are herein amended. Applicant notes that these amendments are neither narrowing amendments nor made for reasons of patentability, and are made for additional clarity, for example, to recite more explicitly the meaning of "reflex algorithm". Applicant respectfully requests reconsideration in view of the herewith presented amendments and remarks.

II. The 35 U.S.C. §103(A) Rejections

The Office Action also maintains the rejection of claims 1-12 under 35 USC 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of Furlong et al. (Clinical Chemistry, 1990), based on the reasons of record.

More specifically, in response to Applicant's arguments filed 9/17/01, the Office Action asserts the following:

> [T]he determination of pathology associated with different possible measurements in "reflex algorithm" is necessarily dependent upon predetermined set of biochemical measurements programmed into software for use by the algorithm, in addition to other different possible measurements, to effect a decision tree such as in a neural network design which provides for feedback

> mechanism including a suggestion to perform other activity or to activate another network structure which Groth refers to as a "feeback connection from conclusive diagnostic unit" (see column 16, lines 42-67) so that further testing, if desired, can be activated into preprogrammed analytical computer software to further analyze a sample. Alternatively, Applicant, by way of admission at page 2 of the specification, discloses that reflex algorithm has been employed in the areas of clinical chemistry and laboratory medicine for the past decade. Therefore, absent evidence to the contrary, the neural network system disclosed by both Groth and Furlong can, otherwise, be designed and programmed to allow reflex algorithm capability such as claimed in the instant invention.

Applicant respectfully submits that even assuming *arguendo* that Lillig, Groth, and Furlong may be combined as asserted in the Office Action, this combination fails to provide all the limitations of Applicant's claimed invention, and further one skilled in the art would not have been motivated to modify such a combination to provide Applicant's claimed invention as a whole, which includes, *inter alia*, an immunoassay analyzer and a clinical chemistry assay analyzer that are controlled according to "reflex algorithm".

Independent claims 1, 9, and 10 have herein been amended to additionally clarify the meaning of "reflex algorithm":

> the reflex algorithm represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set comprising at least one immunoassay measurement or at least one clinical chemistry measurement or at least one immunoassay and at least one clinical chemistry measurement, *wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets*, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps *wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps* [Emphasis added.]

Applicant respectfully submits that Groth's disclosure of the feedback structure employing neural networks in Figure 17 is in stark contrast to a reflex algorithm as claimed. More specifically, as understood by Applicant, if the first neural network structure 224 (together with the conclusive diagnostic unit 226) generates a non-diagnosis indication, then the *identical* set of biochemical marker measurements are run at a later time and the second neural network classifies the results based on the temporal pattern of these later obtained biochemical marker measurements. Thus, since this structure simply provides selectively repeating the *identical* set of markers at a later time, and nonetheless determines AMI according to classification by a trained neural network structure operating on all the marker measurements, it cannot be said to provide a reflex algorithm "wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets".

Nor does this feedback structure of Groth (individually or in view of Furlong and Lillig) teach or suggest a sequence of biochemical marker measurement steps "wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay measurement *type* and/or clinical chemistry measurement *type* not required by another of said plurality of paths of the biochemical marker measurement steps". As may be appreciated, this aspect of a "reflex algorithm" as claimed means that at least one of the paths in the hierarchical decision-tree does not require performing at least one distinct measurement type that is required by another path. More specifically, as explained for example in Applicants' specification at page 23 et seq., a feature of Applicants' invention is that it may eliminate the need to perform additional and distinct biochemical marker tests (e.g., distinct assays that may be unnecessary for providing a diagnosis or indication of pathology), thus providing for, *inter alia*, cost reductions

(e.g., in the example given in the specification, a path requires myoglobin and total CK but neither CKMB nor cTNI measurements, while another path requires myoglobin, total CK and CKMB but does not require any cTNI measurements, while (as a further example) another path requires myoglobin, total CK, CKMB and cTNI). In Groth, however, even assuming *arguendo* that the Figure 17 embodiment provides for a decision tree, *all* the biochemical marker measurement types are run in any case: no "path" eliminates the need for at least one type of measurement.

Simply stated, the feedback structure shown in Figure 17 of Groth (even in view of Furlong and Lillig) does not transform the classification by a neural network into a determination according to a reflex algorithm as claimed. Moreover, Applicant submits that Groth an Furlong, in fact, teach away from Applicant's claimed invention inasmuch as such a neural network paradigm (regardless of feedback or repetition) is directed to classification based on a pre-determined, immutable set of measurements that are fed into a trained neural network for classification, which is diametric to a reflex algorithm wherein determination of a pathology is associated with non-identical biochemical marker measurement steps and/or different paths as claimed.

As noted above, the Office Action alternatively asserts that "Applicant, by way of admission at page 2 of the specification, discloses that reflex algorithm has been employed in the areas of clinical chemistry and laboratory medicine for the past decade . . .[and] [t]herefore, absent evidence to the contrary, the neural network system disclosed by both Groth and Furlong can, otherwise, be designed and programmed to allow reflex algorithm capability such as claimed in the instant invention." Applicants respectfully traverse this ground of rejection at

least insofar as it fails to provide any basis, suggestion, or motivation for how or why it would have been obvious to modify a neural network based system to provide a reflex algorithm. Applicants' statements in the background section of the application in no way admits or suggests that because reflex algorithms have been employed in the areas of clinical chemistry and laboratory medicine that it would somehow be obvious to generate them from neural network models. To the contrary, the background section explains that neural network paradigms are quite distinct from reflex algorithms. Further, Applicants background section statement regarding clinical chemistry and laboratory medicine reflex algorithms are inapposite with respect to a reflex algorithm, as claimed, which includes both clinical chemistry and immunoassay measurements. If the Examiner maintains this position in a subsequent office action, Applicant respectfully requests that the Examiner support this position by an affidavit or a prior art reference.

Regarding this alternative assertion in the Office Action, Applicants further note that, based on the reasons explained above, even assuming *arguendo* that it would have somehow been obvious to generate a non-neural network type algorithm based on the neural network based systems of Groth and Furlong, such an algorithm would not provide a "reflex algorithm" as claimed because, *inter alia*, there is no teaching or suggestion for modifying the systems/algorithm of Groth and Furlong such that "at least two of the biochemical marker measurement steps specify non-identical measurement sets", nor such that "at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps", as claimed by Applicant.

Thus, for at least these reasons, Applicants respectfully submit that even assuming arguendo that Lillig, Groth, and Furlong may be combined as asserted in the Office Action, such a combination would fail to teach all the limitations of Applicant's claimed invention, and there would have been no motivation or suggestion to modify such a combination to provide Applicant's claimed invention as a whole. Accordingly, Applicant respectfully requests that the §103(a) rejection of claims 1-12 be withdrawn.

III. Conclusion

In view of the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. Reconsideration and withdrawal of the Examiner's rejections is respectfully requested and allowance of all pending claims is respectfully submitted.

If any outstanding issues remain, or if the Examiner has any suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number below.

The Examiner's consideration of this matter is gratefully acknowledged.

Respectfully submitted,

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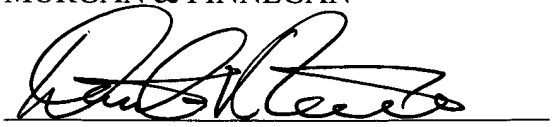
Date: November 21, 2002 By: 

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CLAIM AMENDMENT ANNEX

1. (Twice Amended) A diagnostic system comprising:

an immunoassay analyzer;

a clinical chemistry analyzer;

an automatic sample handling device coupled between said immunoassay analyzer and said clinical chemistry analyzer to allow sharing of samples therebetween; and

a processor in communication with said immunoassay analyzer and said clinical chemistry analyzer, wherein said processor commands said immunoassay analyzer and clinical chemistry analyzer to execute immunoassay and clinical chemistry measurements specified by a program executed by the processor in order to facilitate diagnosis of a pathology for a subject according to a reflex algorithm [which] that includes at least one immunoassay and at least one clinical chemistry assay and that represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set for execution comprising at least one immunoassay measurement or at least one clinical chemistry measurement or at least one immunoassay and at least one clinical chemistry measurement, wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets for execution, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay measurement type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps.

9. (Thrice Amended) A system for executing a sequence of biochemical marker measurement steps to generate an indication of a pathology, [the biochemical marker measurement steps including an immunoassay measurement and a clinical chemistry assay measurement,] each of the biochemical marker measurement steps comprising measuring at least one concentration level or activity of at least one biochemical marker in at least one of a urine, serum, plasma or whole blood sample, the system comprising:

means for performing an immunoassay measurement;

means for performing a clinical chemistry assay measurement;

means for sample handling between the immunoassay measurement means and the clinical chemistry assay measurement means;

means for storing information representing a reflex algorithm indicating a plurality of predetermined sequences of biochemical marker measurements;

means for receiving information concerning outputs from biochemical marker measurements conducted on the immunoassay means and the clinical chemistry assay means;

means for selectively commanding said immunoassay measurement means and said clinical chemistry assay means to perform a specified biochemical marker measurement according to said reflex algorithm; and

means for specifying an indication of the pathology according to the stored information in response to the information concerning outputs from biochemical marker measurements; and

wherein the reflex algorithm represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set for execution comprising at least one immunoassay measurement or at least one clinical chemistry measurement or at least one immunoassay and at least one clinical chemistry measurement, wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets for execution, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay measurement type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps.

10. (Thrice Amended) A system for executing a sequence of biochemical marker measurement steps, [the biochemical marker measurement steps including immunoassay and clinical chemistry assays,] each of the biochemical marker measurement steps comprising measuring at least one concentration level or activity of at least one biochemical marker in at least one of a serum, plasma or whole blood sample obtained from a subject at a time specified by a reflex algorithm, the system comprising:

immunoassay instrumentation that allows automatic execution of an immunoassay

measurement;

clinical chemistry instrumentation that allows automatic execution of a clinical chemistry assay measurement;

a sample handling device coupled between said immunoassay instrumentation and said clinical chemistry instrumentation to allow sharing of samples therebetween;

a computer-readable medium that stores information that represents the reflex algorithm; and

a processor coupled to said immunoassay instrumentation, said clinical chemistry instrumentation, and said computer-readable medium, wherein said processor receives information representative of outputs from biochemical marker measurements conducted on the immunoassay instrumentation and on the clinical chemistry instrumentation, and selectively commands said immunoassay instrumentation and said clinical chemistry instrumentation to execute the biochemical marker measurement according to the reflex algorithm; and

wherein the reflex algorithm represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set comprising at least one immunoassay measurement or at least one clinical chemistry measurement or at least one immunoassay and at least one clinical chemistry measurement, wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay measurement type and/or clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps.